

**REMARKS**

A response to a Restriction Requirement was filed on November 23, 2004, whereby Applicant elected the claims of Group IV, including claim numbers 23-35 and 56-66, with traverse. The Examiner has now forwarded a second Restriction Requirement, whereby further restriction is required.

Applicant's representatives would like to thank Examiner Royds for telephonic conferences, which were held with Examiner Royds on June 7, 2005, June 13, 2005, June 16, 2005 and on June 17, 2005 to discuss this further Restriction Requirement. In particular, Applicant requested confirmation as to why claim numbers 28 and 61 were not included in this Restriction Requirement, since they were part of the originally elected Group IV claims. Furthermore, Applicant also noted that the salicylates, which were also part of the original claim set as elected by way of the first Restriction Requirement, were not included in this second Restriction Requirement. Examiner Royds kindly explained that a Group C claim set drawn to the second agent being an inhibitor of glutamate induced excitotoxicity was inadvertently left out of the Office Action. In addition, the salicylates were inadvertently left out of Section B, Group XVIII. On the basis of this conference, the Examiner noted that Applicant must elect at least one agent from Section A, one agent from Section B and one agent from Section C (as outlined by the Examiner in the telephonic conference and included herewith). Furthermore, Applicant must choose one of the four possible combinations of agents:

- 1) one agent of Section A alone;
- 2) one agent of Section A in combination with one agent of Section B;
- 3) one agent of Section A in combination with one agent of Section C;
- 4) one agent of Section A in combination with one agent of Section B in combination with one agent of Section C.

Accordingly, and further on the basis of the above-noted conference with Examiner Royds, in the present Requirement for Restriction, the Examiner requested election of one of the following groups:

**Section A.** At least one first agent:

- I. Claims 1, 23, 36 and 56, wherein the at least one first agent is minocycline or any tetracycline family derivative capable of crossing the blood brain barrier, classified in class 514, subclass 152, for example.
- II. Claims 1, 23, 36 and 56, wherein the at least one first agent is acetylsalicylic acid or any salicylate which inhibits early phase cell cycle progression, classified in class 514, subclass 165, for example.
- III. Claims 1, 23, 36 and 56, wherein the at least one first agent is sirolimus or any sirolimus derivative capable of inhibiting early cell cycle progression, classified in class 514, subclass 326, for example.
- IV. Claims 1, 23, 36 and 56, wherein the at least one first agent is flavopiridol, classified in class 514, subclass 327, for example.
- V. Claims 1, 23, 36 and 56, wherein the at least one first agent is ciclopirox, classified in class 514, subclass 345, for example.
- VI. Claims 1, 23, 36 and 56, wherein the at least one first agent is a paulone, classified in class 514, various subclasses, depending on the structure, for example.
- VII. Claims 1, 23, 36 and 56, wherein the at least one first agent is indirubin, classified in class 514, subclass 418, for example.
- VIII. Claims 1, 23, 36 and 56, wherein the at least one first agent is fascaplycin, classified in class 514, subclass 280, for example.

- IX. Claims 1, 23, 36 and 56, wherein the at least one first agent is olomoucine, classified in class 514, subclass 263.4, for example.
- X. Claims 1, 23, 36 and 56, wherein the at least one first agent is roscovitine, classified in class 514, subclass 263.4, for example.
- XI. Claims 1, 23, 36 and 56, wherein the at least one first agent is Aragusterol A, classified in class 514, subclass 172, for example.
- XII. Claims 1, 23, 36 and 56, wherein the at least one first agent is valproate, classified in class 514, subclass 557, for example.
- XIII. Claims 1, 23, 36 and 56, wherein the at least one first agent is N-(3-chloro-7-indolyl)-1,4-benzenedisulfamide, classified in class 514, subclass 415, for example.
- XIV. Claims 1, 23, 36 and 56, wherein the at least one first agent is the farnesyl transferase inhibitor R115777, classified in class 514, subclass 312, for example.
- XV. Claims 1, 23, 36 and 56, wherein the at least one first agent is the farnesyl transferase inhibitor SCH66336, classified in class 514, subclass 296, for example.
- XVI. Claims 1, 23, 36 and 56, wherein the at least one first agent is the farnesyl transferase inhibitor BMS-214662, classified in class 514, subclass 221, for example.
- XVII. Claims 1, 23, 36 and 56, wherein the at least one first agent is sodium butyrate, classified in class 514, subclass 557, for example.

The Examiner has also required election of one of the following groups drawn to at least one second agent:

**Section B.** At least one second agent being an anti-inflammatory:

- XVIII. Claims 23, 36 and 56, wherein the at least one second agent is an NSAID selected from the group consisting of salicylates, ibuprofen, naproxen, celecoxib, rofecoxib, sulindac, piroxicam, indomethacin, etodolac, nabumetone, tolmetin, diclofenac, ketoprofen, apazone and meloxicam, classified in class 514, subclasses 226.5, 406, 420 or 570, for example, depending on the agent used.
- XIX. Claims 23, 36 and 56, wherein the at least one second agent is prednisone, classified in class 514, subclass 179, for example.
- XX. Claims 23, 36 and 56, wherein the at least one second agent is cyclosporine A, classified in class 514, subclass 11, for example.
- XXI. Claims 23, 36 and 56, wherein the at least one second agent is tacrolimus, classified in class 514, subclass 326, for example.

**Section C.** At least one second agent being an inhibitor of glutamate induced excitotoxicity:

- XXII. Claims 28 and 61, wherein the at least one second agent is memantine.
- XXIII. Claims 28 and 61, wherein the at least one second agent is neramexane.
- XXIV. Claims 28 and 61, wherein the at least one second agent is amantadine.
- XXV. Claims 28 and 61, wherein the at least one second agent is riluzole.
- XXVI. Claims 28 and 61, wherein the at least one second agent is MK801.
- XXVII. Claims 28 and 61, wherein the at least one second agent is ketamine.
- XXVIII. Claims 28 and 61, wherein the at least one second agent is dextromethorphan.
- XXIX. Claims 28 and 61, wherein the at least one second agent is dextrorphan.
- XXX. Claims 28 and 61, wherein the at least one second agent is phencyclidine.

XXXI. Claims 28 and 61, wherein the at least one second agent is dexanabinol (HU-211).

Furthermore, as noted in the telephonic discussion with the Examiner, Applicant must choose one of the four possible combinations of agents:

- 1) one agent of Section A alone;
- 2) one agent of Section A in combination with one agent of Section B;
- 3) one agent of Section A in combination with one agent of Section C;
- 4) one agent of Section A in combination with one agent of Section B in combination with one agent of Section C.

Applicant elects to prosecute the invention of:

Section A (the at least one first agent): **Group I, claims 1, 23, 36 and 56, wherein the at least one first agent is minocycline or any tetracycline family derivative capable of crossing the blood brain barrier,**

Section B (the at least one second agent, which is an anti-inflammatory): **Group XVIII, claims 23, 36 and 56, wherein the at least one second agent is salicylates.**

Section C (the at least one second agent, which is an inhibitor of glutamate induced excitotoxicity): **Group XXII, claims 28 and 61, wherein the at least one second agent is memantine.**

With respect to the requirement for choosing one of the four possible combinations of agents, **Applicant elects the combination noted above in 4) one agent of Section A in combination with one agent of Section B in combination with one agent of Section C.**

Applicant traverses the Restriction Requirement and respectfully requests reconsideration of the Requirement for Restriction, for the reasons provided as follows.

Under 35 U.S.C. §121 "two or more independent and distinct inventions ... in one Application may ... be restricted to one of the inventions." Inventions are "'independent'" if "there is no disclosed relationship between the two or more subjects disclosed" (MPEP 802.01). The term "'distinct'" means that "two or more subjects as

disclosed are related ... but are capable of separate manufacture, use or sale as claimed, AND ARE PATENTABLE OVER EACH OTHER" (MPEP 802.01) (emphasis in original). However, even with patentably distinct inventions, restriction is not required unless one of the following reasons appear (MPEP 808.02):

1. Separate classification
2. Separate status in the art; or
3. Different field of search.

Further, under Patent Office Examining Procedures, "[i]f the Search and Examination of an entire Application can be made without serious burden, the Examiner must examine it on the merits, even though it includes claims to distinct or independent inventions" (MPEP 803, Rev. 8, May 1988) (emphasis added).

Applicant respectfully submits that the groups designated by the Examiner fail to define compositions and methods, with properties so distinct as to warrant separate Examination and Search. The Examiner's assertions to the contrary notwithstanding, Applicants respectfully submit that conjoint examination and inclusion of all of the claims of the present Application would not present an undue burden on the Examiner, and accordingly, withdrawal of the Requirement for Restriction is in order.

No fees are believed to be necessitated by the foregoing Response. However, should this be erroneous, authorization is hereby given to charge Deposit Account No. 11-1153 for any underpayment, or credit any overages.

In view of the above, withdrawal of the Requirement for Restriction is requested, and an early action on the merits of the claims is courteously solicited.

Respectfully submitted,



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